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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/764,405	01/23/2004	John Chen	1001.1677101	9509

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EXAMINER	
HALL, DEANNA K	
ART UNIT	**PAPER NUMBER**
3767	

MAIL DATE	DELIVERY MODE
07/25/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/764,405	CHEN ET AL.	
	Examiner	Art Unit	
	Deanna K. Hall	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 January 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *23 January 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *May 17, 2004; May 11, 2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Information Disclosure Statement

1. The information disclosure statements (IDS) submitted on May 17, 2004 and May 11, 2005 are in compliance with the provisions of 37 CFR 1.97(b). Accordingly, the IDS is being considered by the Examiner.

Oath/Declaration

2. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

> The oath or declaration is defective because:
> It does not state that the person making the oath or declaration acknowledges the duty to disclose to the Office all information known to the person to be material to **patentability** as defined in **37 CFR 1.56**.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. **Claims 1-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Saab (US 5,499,973) in view of Lee (US 6,217,547).** Saab discloses:

A first tubular member 12 having a proximal portion and a distal portion with a lumen 18 extending between the proximal portion and the distal portion; a balloon 16 having a proximal and distal waist length C4 L50-55 and an expandable region therebetween 20; and a polymeric tie layer 30, 32, 34.

Saab does not directly show that the tie layer comprises a polyester polymer and a polyamide polymer. However, Saab does disclose that relying on a set of heat-shrunk polymeric stiffening bands does not restrict the choice of materials for the inner and outer tubular members or the balloon element C6 L5-12. Saab goes on to state that, juxtaposed to Solar et al. (US 4,976,690), the "waist" portion of the catheter must be fabricated of different material as the balloon element to achieve the desired degree of stiffness C5 L15-20. Lee, in the analogous art, teaches not only that the tubular member can be formed from a polyamide or a polyether block amide C3 L14-24, but also teaches that the balloon can be formed of PET or copolyester C3 L67-C4 L2 and that lubricous polymeric materials frequently lack the ability to readily bond to incompatible polymeric materials such as polyethylene terephthalate (PET) C1 L64- C2 L4, thus if the balloon was fabricated of PET, a material that is different and non-lubricous must be used in the tie layer for optimal bonding. Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to have modified the device of Saab with the teachings of Lee that the tie layer comprises a polyester polymer C3 L53-54 and a polyamide polymer C3 L14-15 for optimal bonding.

5. Claims 6-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Saab in view of Lee.

Saab in view of Lee discloses the invention as substantially claimed (see above). Further, Saab discloses two layers or a heat-shrunk sleeve directly over the first tubular member C6 L13-49 (claim 7).

However, the combination of Saab/Lee does not teach the tie layer comprising a copolymer of polyester and polyamide with the polyester layer comprising a polybutylene terephthalate. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the polymeric blends of Lee since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 227 F.2d 197, 125 USPQ 416 (CCPA 1960).

6. **Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Saab in view of Lee.** Saab discloses the invention as substantially claimed (see above).

Saab discloses: A first tubular member 12 having a proximal portion and a distal portion with a lumen 18 extending between the proximal portion and the distal portion; a balloon 16 having a proximal and distal waist length C4 L50-55 and an expandable region therebetween 20; and a polymeric tie layer 30, 32, 34.

Saab does not directly show that the tie layer comprises a polyester polymer and a polyamide polymer. However, Saab does disclose that relying on a set of heat-shrunk

polymeric stiffening bands does not restrict the choice of materials for the inner and outer tubular members or the balloon element C6 L5-12. Saab goes on to state that, juxtaposed to Solar et al. (US 4,976,690), the "waist" portion of the catheter must be fabricated of different material as the balloon element to achieve the desired degree of stiffness C5 L15-20. Lee, in the analogous art, teaches that the balloon can be formed of PET or copolyester C3 L67-C4 L2 and that lubricous polymeric materials frequently lack the ability to readily bond to incompatible polymeric materials such as polyethylene terephthalate (PET) C1 L64- C2 L4, thus if the balloon was fabricated of PET, a material that is different and non-lubricous must be used in the tie layer for optimal bonding. Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to have modified the device of Saab with the teachings of Lee that the tie layer comprises a polyester polymer C3 L53-54 and a polyamide polymer C3 L14-15 for optimal bonding.

7. Claims 11-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Saab in view of Lee.

Saab in view of Lee discloses the invention as substantially claimed (see above). Further, Saab discloses two layers or a heat-shrunk sleeve directly over the first tubular member C6 L13-49 (claim 12).

However, the combination of Saab/Lee does not teach the tie layer comprising a copolymer of polyester and polyamide with the polyester layer comprising a polybutylene terephthalate. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the polymeric blends of Lee since it

has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 227 F.2d 197, 125 USPQ 416 (CCPA 1960).

8. **Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Saab in view of Lee.** Saab discloses the invention as substantially claimed (see above).

Saab discloses: A first polyamide tubular member 12 having a proximal portion and a distal portion with a lumen 18 extending between the proximal portion and the distal portion; a balloon 16 having a proximal and distal waist length C4 L50-55 and an expandable region therebetween 20; and a polymeric tie layer 30, 32, 34.

Saab does not directly show that the tie layer comprises a polyester polymer and a polyamide polymer. However, Saab does disclose that relying on a set of heat-shrunk polymeric stiffening bands does not restrict the choice of materials for the inner and outer tubular members or the balloon element C6 L5-12. Saab goes on to state that, juxtaposed to Solar et al. (US 4,976,690), the "waist" portion of the catheter must be fabricated of different material as the balloon element to achieve the desired degree of stiffness C5 L15-20. Lee, in the analogous art, teaches that the balloon can be formed of PET or copolyester C3 L67-C4 L2 and that lubricous polymeric materials frequently lack the ability to readily bond to incompatible polymeric materials such as polyethylene terephthalate (PET) C1 L64- C2 L4, thus if the balloon was fabricated of PET, a material that is different and non-lubricous must be used in the tie layer for optimal bonding. Therefore, it would have been obvious to a person having ordinary skill in the art at the

time the invention was made to have modified the device of Saab with the teachings of Lee that the tie layer comprises a polyester polymer C3 L53-54 and a polyamide polymer C3 L14-15 for optimal bonding.

9. Claims 16-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Saab in view of Lee.

Saab in view of Lee discloses the invention as substantially claimed (see above). Further, Saab discloses two layers or a heat-shrunk sleeve directly over the first tubular member C6 L13-49 (claim 17). Also, Saab discloses heat bonding polymeric sleeves around the tubular member C4 L3-17 (claim 20).

However, the combination of Saab/Lee does not teach the tie layer comprising a copolymer of polyester and polyamide with the polyester layer comprising a polybutylene terephthalate. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the polymeric blends of Lee since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 227 F.2d 197, 125 USPQ 416 (CCPA 1960).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deanna K. Hall whose telephone number is 571-272-2819. The examiner can normally be reached on M-F 8:00am-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, LoAn Thanh can be reached on 571-272-4966. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Deanna K. Hall
Examiner
AU 3767

dkh

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PRIMARY EXAM